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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,042	03/13/2006	Shubha Anand	BJS-620-406	8188

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EXAMINER	
LOVE, TREVOR M	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,042	ANAND ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *10-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Applicant's response filed 06/08/2009

Claims 1-32 are pending. Claims 10-32 are withdrawn as being drawn to non-elect species. Claims 1-9 are currently under consideration. As a point of clarification, claim 10 was withdrawn per Applicant's response (12/09/2007) to the species election (11/05/2007) wherein Applicant elected breast cancer.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauf et al (Journal of Cell Biology) (IDS reference).

Hauf discloses that hesperadin can be used to allow cells treated with paclitaxel to stabilize at a faster rate based on the interaction with the spindle assembly checkpoint (see page 288, column 1, last two paragraphs). The findings of Hauf indicate that hesperadin inhibits Aurora B and that Aurora B function is required for spindle assembly in human cells (see page 283, second column, last sentence). Said combination of paclitaxel and heperadin would have an effect on breast cancer cells. This reads on **instant claims 1-5 and 8-9**. .

Hauf fails to directly disclose delivery of said composition to an individual.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the composition to an individual. One would have been motivated to do so since Hauf teaches the advantages of the composition on

breast cancer cells, which effect individuals. Furthermore, Hauf identifies a nexus between hesperadin, Aurora B function, and spindle assembly in human cells (see page 283, second column, last sentence). There would be a reasonable expectation of success in the combination since cell lines are normally tested prior to administration to an individual in order to determine their overall safety and efficiency.

Response to Arguments and Declarations

Applicant argues in the remarks, and the 131 and 132 declarations filed 06/08/2009 that the Anand et al reference is not citable against the presently claimed invention (see Remarks, page 4, paragraph 2). Applicant states that the 131 declaration, at least to the extent it may be found in the cited Hauf et al reference, was described in the Applicants earlier publication of Anand et al. Applicant argues that the Anand et al reference establishes Applicant's prior inventorship. Applicant's arguments and declarations have been fully considered and are not found persuasive. First, it is noted that the Anand et al reference is not being relied upon in making the rejection, wherein it is noted that Hauf et al directly teaches that paclitaxel is useful in the treatment of breast cancer. Secondly, it is noted that Applicant is attempting to antedate the Hauf et al reference, however, Hauf et al is unable to be antedated by Anand et al since Anand et al does not provide sufficient teaching for the invention as currently claimed. Applicant is currently claiming a combination of taxol and Aurora kinase inhibitor, which is taught by Hauf et al, whereas Anand et al, while being directed to the mitotic spindle assembly inhibitor paclitaxel, does not teach the use of Aurora

kinase inhibitors. Anand et al rather addresses the negative effects associated with Aurura-A over-expression by utilizing *BUB1* which affects the spindle checkpoint which the Aurura-A is having a negative effect upon, rather than inhibiting Aurura kinase. Therefore, Applicant's arguments are not found persuasive since Anand et al is not teaching the same invention/combination as either Hauf et al or the instantly claimed invention.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauf et al (Journal of Cell Biology) (IDS reference) as set forth above for instant claims 1-5, in further view of Slamon et al (N.E.J.M.) as evidenced by Lange et al (EMBO Journal).

The teachings of Hauf is set forth above wherein it is further noted that Hauf teaches that Aurora B antibodies have been utilized to overcome nocodazole-induced arrest in cultured cells which Hauf indicates suggests a direct role of Aurora B in the spindle assembly checkpoint (see page 292, first column, second paragraph, last sentence).

Hauf fails to directly disclose that the Aurora kinase inhibitor is an antibody.

Slamon teaches a recombinant monoclonal antibody is utilized in breast cancer patients to aid in correcting the over expression of HER2 which is over-expressed in 25 to 30% of breast cancers (see Abstract, first eight lines). Lange shows that members of the Aurora Kinase family are over-expressed in tumor types, such as human colorectal,

breast, prostate, and ovarian cancers (see page 5372, first column, last paragraph, fourth sentence).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize antibodies to mediate the over-expression of Aurora in a breast cancer patient. One would have been motivated to do so since Slamon teaches the mediation of HER2 over-expression in breast cancer patients by the utilization of antibodies. There would be a reasonable expectation of success in the combination since Applicant identified in the instant specification that there are many well known methods of acquiring antibodies (see instant specification, page 7, lines 1-13). Furthermore, it was well known in the art that Aurora kinases are over-expressed in breast cancer patients, and it is also known in the art that antibodies can be used to mediate over-expression of HER2. One would have looked to various options to overcome the Aurora over-expression, such as antibodies. One would have particularly looked to antibodies since Slamon teaches a method of reducing HER2 gene over-expression by using antibodies (see Slamon (see page 783, last paragraph through 784, first paragraph).

Response to Arguments and Declarations

Response to Applicant's arguments and declarations are set forth above.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauf et al (Journal of Cell Biology) (IDS reference) as set forth above for instant claims

1-5, in further view of Obermiller et al (Breast Cancer Res) as evidenced by Lange et al (EMBO Journal).

The teachings of Hauf is set forth above.

Hauf fails to directly disclose that the Aurora kinase inhibitor is a sense or anti-sense nucleic acid.

Obermiller teaches that gene therapy is useful when trying to correct specific molecular defects that contribute to the cause or progression of cancer, specifically, breast cancer (see abstract).

It was well known in the art that Aurora kinases are over-expressed in breast cancer patients, and it is also known in the art that gene therapy can be used to can provide selective targeting of specific issues, such as Aurora kinase over-expression. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize sense or anti-sense nucleic acids to mediate the over-expression of Aurora in a breast cancer patient. One would have been motivated to do so since Obermiller teaches that gene therapy provides the ability to correct specific molecular defects that contribute to the cause or progression of cancer, this would include the over-expression of Aurora kinase in breast cancer patients. There would be a reasonable expectation of success in the combination since Applicant identified in the instant specification that there are many well known methods of down-regulating gene expression (see instant specification, page 8, lines 6-9 and page 10, lines 21-27).

Response to Arguments and Declarations

Response to Applicant's arguments and declarations are set forth above.

Conclusion

No claims allowed. All claims rejected. No claims objected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611